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CONDITIONS FOR A PLANT INVOLVED IN THE PRODUCTION OF PROCESSING OF CATEGORY 2 ANIMAL BY-PRODUCTS

GOVERNING EU AND NATIONAL LEGISLATION:

The European Union (Animal By-Products) Regulation 2014 (S.I. No. 187 of 2014) and in accordance with Regulation (EC) No. 1069 of 2009 and Regulation (EU) No. 142 of 2011.

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Milk & Meat Hygiene/ABP/TSE Division

CONDITIONS FOR A PLANT INVOLVED IN THE PROCESSING OF THE PRODUCTION OF PROCESSING CATEGORY 3 ANIMAL BY-PRODUCTS

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GLOSSARY OF TERMS

A

'**Animal By-Products**' (**ABP**) means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen.

B

'**Batch**' means a unit of production produced in a single plant using uniform production parameters, such as the origin of the materials, or a number of such units, when produced in continuous order in a single plant and stored together as a shipping unit;

C

'**Competent Authority**' means the central authority of a Member State competent to ensure compliance with the requirements of EU ABP Regulations or any authority to which that competence has been delegated; it also includes, where appropriate, the corresponding authority of a third country;

D

'DAFM' means the Department of Agriculture, Food and the Marine;

'Derived products' means products obtained from one or more treatments, transformations or steps of processing of animal by-products;

E

'**Establishment**' or '**plan**t' means any place where any operation involving the handling of animal by-products or derived products is carried out, other than a fishing vessel;

'EU' means the European Union.

O

'Operator' means the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users.

SECTION 1

GENERAL INFORMATION, REQUIREMENTS AND HACCP

1.1 GENERAL INFORMATION AND REQUIREMENTS

- A plant involved in the production of processing of Category 2 material must be approved by the Department of Agriculture, Food and the Marine (DAFM) and hold a valid certificate of approval in accordance with Article 24 (a) of Regulation (EC) No. 1069/2009.

- The operator must comply with all relevant requirements listed in National legislation European Union (Animal By-Products) Regulations 2014 (S.I. No. 187 of 2014) and in accordance with EU Legislation (Regulation (EC) No. 1069/2009 and Regulation (EU) No. 142/2011).

- Licenses and authorisations required to operate must be valid from all relevant licensing authorities while the plant is operational.

- The operator must notify DAFM immediately if significant changes are proposed to plant activities.

- The operator must notify DAFM immediately if the plant is no longer to be used for handling ABPs. The plant must be decommissioned at this time and prior to use for any other activity. The operator will organise the decommissioning of the plant and clean up of the site and buildings as well as safe disposal of all equipment in a reasonable time period, under the supervision of DAFM.

- All records required in the context of the Animal By-Products (ABP) Regulations must be retained in the plant's office for a period of 3 years. Records must be made available for inspection by DAFM staff.

- The operator must provide data and statistics to DAFM as and when required and in whichever format requested.

1.2 HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

- The operator must design, document and implement a HACCP plan incorporating all the following elements:

  a) identify any hazards that must be prevented, eliminated or reduced to acceptable levels;
  b) identify the critical control points (CCPs) at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels;
  c) establish critical limits at CCPs which separate acceptability from unacceptability, for the prevention, elimination or reduction of identified hazards;
  d) establish and implement effective monitoring procedures at CCPs;

e) establish corrective action when monitoring indicates that a CCP is not under control;
f) establish procedures to verify that the measures outlined in points (a) to (e) are complete, working effectively and in accordance with Regulation (EC) No. 1069/2009 and implementing Regulation (EU) No. 142/2011. Verification procedures shall be carried out regularly;
g) establish documents and records proportionate to the nature and size of the businesses to demonstrate the effective application of the measures set out in points (a) to (f).

This HACCP plan should also describe and document:

- clear responsibilities for all previous points and actions;
- the HACCP team and frequency of routine HACCP review;
- HACCP training;
- detailed process flow diagrams;
- detailed product descriptions and end-usages, including labelling of product.

The HACCP should be underpinned by a good set of pre-requisite programme procedures (for example hygiene, maintenance, traceability, calibration, final product testing).

When any modification is made to a product, process or any stage of production, processing, storage or distribution, the operator shall review their procedures and make the necessary changes and the HACCP plan should be routinely reviewed at least once yearly.

A DAFM veterinary inspector from the Regional Veterinary Office should sanction any proposed significant changes to the HACCP plan in advance of their implementation and should be provided with an up-to-date copy of the HACCP plan.

SECTION 2

BIOSECURITY, PLANT STRUCTURE, HYGIENE AND TRANSPORT

2.1 PERIMETER

- The premises must be located so that it is adequately separated from public highways and other appropriate premises sufficient to prevent cross-contamination of food and feed for humans and animals respectively. Co-location on other ABP sites is dealt with on a case by case basis. Animals must not be allowed access to the plant.

  In particular, processing plants must not be situated on the same site as slaughterhouses or other establishments which have been approved or registered in accordance with Regulation (EC) No. 852/2004 or Regulation (EC) No. 853/2004, unless the risks to public and animal health resulting from the processing of ABP, which originate from such slaughterhouses or other establishments, are mitigated by compliance with at least the following conditions:

  (i) the processing plant must be physically separated from the slaughterhouse or other establishment, where appropriate by locating the processing plant in a building that is completely separated from the slaughterhouse or other establishment;
  (ii) the following must be installed and operated in the processing plant:
  — a conveyer system which links the processing plant to the slaughterhouse or other establishment and which may not be by-passed,
  — separate entrances, reception bays, equipment and exits for both the processing plant and the slaughterhouse or establishment;
  (iii) measures must be taken to prevent the spreading of risks through the operation of personnel which is employed in the processing plant, slaughterhouse or other establishment.

2.2 BUILDINGS/STRUCTURAL

- There must be a sufficiently large covered space to receive, handle and store the ABP. All ABP must be under cover.

- All buildings must be maintained clean and in good condition and any necessary repairs must be made on a regular basis.

- The floors must be smooth and sloped to facilitate the drainage of liquids. The inner walls must be smooth, clean and well maintained.

- The layout of plants must ensure the total separation of Category 2 material from all other materials from reception until dispatch. There must be total separation between each category of ABP. Any Category 3 material that is mixed with Category 2 material is automatically treated as Category 2 material.

- There must be adequate separation between the area of the plant where incoming material for handling is unloaded and the areas set aside for the handling and the storage of material and derived products.

- Suitable office facilities where an examination of records can take place must be provided on site.

2.3 PLANT HYGIENE

- The operator must ensure that a hygiene plan has been designed and implemented effectively for all areas of the plant.

- All handling, processing, storage locations and equipment must be emptied and cleaned regularly to the extent necessary to ensure hygienic practice.

2.4 PERSONNEL AND WORKFLOWS

- The operator must implement effective procedures and training plans for all operatives employed or subcontracted, ensuring to focus the procedures and training on:
  - safe handling of ABP and derived products;
  - supervision of intake, processing, storage, dispatch and final product sampling and testing;

- Operatives must use suitable dedicated protective clothing, when handling ABP which must be removed/cleaned/disinfected or discarded before leaving the plant.

- Footbaths/bootwashes must be provided at all entrances and exits to the plant.

- There must be access to adequate facilities for personal hygiene including lavatories, changing rooms and washbasins for staff. The washing facilities must be equipped with hot water, soap and paper towels.

2.5 PESTS AND BIRDS

- The operator must have a documented rodent control program in place which includes the following:
  - a bait map;
  - service schedule for bait points;
  - service records for bait points.

2.6 ABP TRANSPORT AND SIGNAGE

- Operators transporting ABP to the plant or from the plant must be registered ABP hauliers and listed on DAFM's animal by-products transport register and must not enter the plant unless registered.

- The operator must maintain receptacle registers for each ABP haulier used. (Each haulier must provide each ABP plant they service with a copy of the receptacle register which should contain the following information:

  - container number;
  - receptacle chassis number (where applicable);
  - authorised ABP or derived product category;
  - registered owner;
  - date of listing/commission;
  - date of delisting/decommission;
  - date of cleaning and disinfection as indicated on cleaning certificate at time of delisting.

- ABP transport vehicles must be designed so as to prevent any accidental discharge of organic material or liquids to the environment.

- The operator must have a system for cleaning and disinfecting the vehicles or reusable containers or receptacles in which ABP are transported.

- Transport vehicles or containers must be dedicated to the carriage of a single Category of ABP or derived (final) product. Raw and processed product should not be transported in the same vehicle or container unless the ABP or derived product is packaged in sealed, leakproof packaging in both instances (preventing cross-contamination). Transport vehicles, receptacles and containers must be covered and leak proof and permanently and prominently marked on both sides appropriately, as follows:

  INCOMING MATERIAL:

  Raw ABP (Category 2 ABP)
  - haulier registration code[1] and receptacle number
  - the Category of ABP as well as the applicable ancillary wording
    Examples:
    "CATEGORY 2 MATERIAL not for Human Consumption"

  Raw ABP (Category 3 ABP only)
  - haulier registration code[2] and receptacle number
  - the Category of ABP as well as the applicable ancillary wording
    Examples:
    "CATEGORY 3 MATERIAL not for Human Consumption"

[1] The haulier must be officially registered with the Department of Agriculture, Food & Marine.
[2] The haulier must be officially registered with the Department of Agriculture, Food & Marine.

Non-ruminant fallen animals (Category 2 ABP)

- haulier registration code[3] and receptacle number
- the Category of ABP as well as the applicable ancillary wording
  Examples:
  "CATEGORY 2 MATERIAL not for Human Consumption"

OUTGOING PRODUCTS:

- haulier registration code[4] and receptacle number
- the Category of ABP as well as the applicable ancillary wording
  Examples:
  "CATEGORY 2 MATERIAL Not For animal Consumption"

- ABP must not be stored overnight in transport vehicles or transferred between vehicles (this constitutes handling) or stored at premises other than those approved by DAFM.

- All storage tanks for rendered fat must be labelled appropriately and in accordance with category of ABP:

  "CATEGORY 2 Material Not For Human Consumption"

  Upon re-dedicating a storage tank to the storage of lower risk ABP category a full disinfection and decontamination protocol, pre-approved by a DAFM authorised officer, must be implemented and under the supervision of DAFM.

2.7 PLANT WASTE DISPOSAL

- All waste ABP from the plant must be disposed of appropriately in compliance with National and EU legislation and in a way that mitigates risk. Traceability of waste disposal must be ensured.

- The operator must maintain and implement measures to prohibit the disposal of ABP or derived products via the waste water system. This should be achieved by the use of drain traps or screens with apertures with a filter pore or a mesh size of no more than 6 mm (or an equivalent system). Blood and milk may not be disposed of via the waste water stream.

  Waste water that has passed through the screen is no longer regarded as ABP. However, the operator has a responsibility to ensure that waste water is treated in accordance with relevant Community environmental legislation.

[3] The haulier must be officially registered with the Department of Agriculture, Food & Marine.
[4] The haulier must be officially registered with the Department of Agriculture, Food & Marine.

SECTION 3

INTAKE

3.1 RAW MATERIAL INTAKE PROCEDURES

- In addition to non-ABP materials, only the raw materials described in Article 9 (Category 2) and Article 10 (Category 3) of Regulation (EC) No. 1069/2009 may be accepted into the plant to be used for processing. All should be considered Category 2 ABP upon entry to the plant.

- The operator must organise for documentary and visual checks on raw material consignments to verify that only raw material or derived product be allowed in this approval and which are safe will be accepted into the plant. material), hazardous material and catering waste are not allowed into the plant.

3.2 DOCUMENTATION

- All ABP material delivered to the plant must be accompanied by a completed commercial document which meets the requirements as laid down in Annex VIII Chapter III of Regulation (EU) No. 142/2011, and, when required by the legislation, a health certificate.

  Commercial documents must specify:
  - the name and address of the consignor and approval number of the plant (if applicable);
  - the name and address of the consignee and plant approval number (if applicable);
  - the name and address of the carrier (haulier) and the registration number of the vehicle;
  - the quantity/weight of the material;
  - the date of dispatch;
  - the container number (if applicable);
  - the seal number (if applicable);
  - the category of the material;
  - a description of the material;
  - signature of the consignor;
  - signature of carrier (haulier).

  Four copies of the commercial document must be produced.

  Relevant Trader Notices (TN01/2015) can be found on the DAFM website by using the following link:
  http://www.agriculture.gov.ie/agri-foodindustry/animalbyproducts/animalbyproducts-tradernotices/

A separate commercial document must be completed for each consignment of material collected in the case of mixed loads. The consignor should send the original plus two copies with the ABP and retain the final copy. The transporter retains one copy and hands the original plus a copy to the receiver. The receiver should keep the original, sign and return the copy to the producer as proof of arrival of the consignment.

- The operator should fulfill obligations describing the proof of arrival of raw material consignments. This may involve return of a plant-stamped commercial document or TRACES message to the consignor of the material if from another MS.

- The operator must keep an up-to-date intake register, completed appropriately, in chronological order and should include:
  - a description of the material (including species of animal(s)) and quantities;
  - the category of incoming material;
  - dates of intake;
  - a batch reference or consignment number if appropriate;
  - a health certificate or commercial document reference number;
  - the name and address and country of the premises of origin (and approval number if applicable);
  - the name and address of the carrier/haulier and the receptacle registration number (if applicable);
  - date of notification of the Regional Veterinary Officer of intake of material (if relevant);
  - weights of consignments of incoming material (preferably using a plant's own weighbridge).

- The operator must establish a system to notify the Competent Authority (Regional Veterinary Officer) if imported[5] ABP/derived products are received on site. An Article 48 licence must be in place authorising the operator to import Category 2 ABP.

  In the case of ABP or derived product being dispatched to other EU countries or third countries, the EU commercial document must be used and a DOCOM message generated on TRACES NT by the business operator or the CA.

  The operator must retain proof of destination for all animal by-product consignments or consignments of products manufactured or derived from ABPs dispatched from the plant. This proof of destination would typically be the signed or stamped copy of the commercial document returned by the customer (consignee) or notification of arrival on the TRACES system.

5 Imported products are products received from non-EU countries.

SECTION 4

PROCESSING/HANDLING

4.1 PROCESSING/HANDLING REQUIREMENTS

- The operator must not engage in activities other than the acceptance, sorting, processing, temporary storage and dispatching of ABP and derived products.

- All raw materials must be processed using the equipment used and tested during validation. If equipment is modified or replaced any such modifications or replacements should be notified in writing in advance to a DAFM authorised officer who will determine whether validation should be repeated.

- The following minimum process parameters must be met:

  - All raw materials must undergo pressure sterilisation during processing;
  - All material undergoing heat treatment must be reduced in size in advance using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded.
  - An adequate safety system must be in place to ensure pressure sterilisation of all material following reduction in size in accordance with the previous point.
  - The parameters required for pressure sterilisation are as follows:-
    - Animal by-products with the particle size of no greater than 50 millimetres must be heated to a core temperature of more than 133ºC for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars. The pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ('saturated steam'); the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.
  - At all times while the plant is operational tamper-proof measuring equipment as well as recording devices to record continuously the results of these measurements must be working, measuring the parameters outlined in the previous bullet point and must do so in a way that they remain accessible for the purpose of checks and official controls.
  - The processing plant must retain at all times sufficient production capacity for hot water and steam for the processing of animal by-products, while operational.

- GTH Addition, Validation[6], Monitoring[7] (whether designated a CCP or not) and Verification[8] must be documented in a Standard Operating Procedure by the plant.

[6]Validation is the step taken, typically for the first time or upon modification of the levels of GTH addition, to demonstrate the soundness of the system i.e. this should be a documented, recorded approach proving by means of final product testing that monitoring routines of GTH addition at a specific defined level will consistently achieve legal levels of GTH in final products.
[7]This is the real-time monitoring routine that will be employed. to demonstrate via records. that circumstances proven to achieve legal levels of GTH in final products at the time of validation are being consistently achieved, and where these circumstances are not met to trigger corrective actions.
[8]Verification for GTH should be achieved by means of routine sampling of final products for GTH to demonstrate that the system is working or to identify that it isn't so as to trigger re-validation.

This operating procedure must be provided to the authorised officer who should agree it.

The operating procedure must incorporate the following elements:-

- A Validation plan and records of said validation from which the rate at which GTH will be added is derived.
- A description of how real-time monitoring of GTH addition will take place, the frequency at which it will take place and the records that will be retained to demonstrate compliance with legislation & validation parameters.
- Defined Pre-determined Corrective Actions in the event monitoring results indicate that sufficient GTH may not have been added in acceptable levels.
- A description of how the plant verifies the GTH addition system by means of final product testing, the frequency at which this takes place and the laboratory used as well as the documented Sampling Apparatus and Sample Taking Procedure for verification.
- **External /Private Laboratories carrying out non-microbiological testing for DAFM regulated ABP premises i.e. GTH, Total Insoluble Impurities & Dioxins must be accredited to internationally recognised standards. A copy of the accreditation certificate, outlining the scope of the accreditation (what they are accredited to test for and the method used) and the matrices concerned (which ABP's the lab. can test for using these methods) must be kept on file and be available**
- Is there an up-to-date Accreditation Certificate available?

Defined Pre-determined Corrective Actions, including re-validation, in the event of verification indicating that there is insufficient GTH present in final products.

- A plan for Insoluble Impurities Testing of Rendered Fat Final Product (whether designated a CCP or not) must be documented in a Standard Operating Procedure by the plant.

  This operating procedure must be provided to the authorized officer who should agree it.

  The operating procedure must incorporate the following elements: -

  - Definition of a batch. (A batch is taken as a volumetric measurement. It will not suffice for a batch to be defined in general terms as a week's production or any given period of time. A batch should be defined as follows:
    - A tallow tank on the processing plant site or
    - A tallow road tanker or
    - A tallow tank in a tallow storage facility)
  - Documented Sampling Apparatus and Sample Taking Procedure.
  - Documented Laboratory Testing procedure and the laboratory to be employed to carry out said test. (The testing procedure must be one that is internationally accredited by an accreditation body. Where processing plants are using their own on-site laboratory verification of testing at this on-site laboratory must take place by comparison with an external iso-accredited independent laboratory).

- **External /Private Laboratories carrying out non-microbiological testing for DAFM regulated ABP premises i.e. GTH, Total Insoluble Impurities and Dioxins must be accredited to internationally recognised standards. A copy of the accreditation certificate, outlining the scope of the accreditation (what they are accredited to test for and the method used) and the matrices concerned (which ABP's the lab. can test for using these methods) must be kept on file and be available.**
- Is there an up-to-date Accreditation Certificate available outlining the Scope and Matrices of the accreditation?

Defined Pre-determined Corrective Actions in the event of test results being non-compliant.

- The plant must be authorized by DAFM to combust rendered fats in a thermal boiler on site.

  If the plant has been authorized in this way all rendered fats to be combusted on site must
  a. have been purified in such a way that the maximum level of remaining total insoluble impurities does not exceed 0.15 % in weight & the plant should be in possession of documented evidence of this.
  b. be vaporised in a steam-raising boiler and combusted at a temperature of at least 1100 °C for at least 0,2 seconds or at a temperature of 850°C for at least 2 seconds.

4.2 EQUIPMENT

- Management must ensure that all measuring devices including weighbridges are calibrated and confirmed to be working effectively at least once every 12 months.
- If any significant changes to equipment or buildings are intended, the operator should contact Milk and Meat Hygiene/ABP/TSE Division to describe the changes; said changes must be sanctioned by an authorised officer prior to taking place.

4.3 CROSS-CONTAMINATION/BY-PASS

- All necessary measures must be taken to prevent contamination and the spreading of diseases communicable to humans or animals, throughout the production chain.

SECTION 5

STORAGE, DISPATCH AND TRACEABILITY/RECALL

5.1 DISPATCH PROCEDURES

- The operator must ensure that ABP or products manufactured or derived from ABP, dispatched from the plant, are traceable and must be either used or disposed of safely and in compliance with National and EU legislation. The prescribed end-usages are set out as follows:
  - disposal as waste by incineration;
  - disposal by co-incineration;
  - disposal in a authorised landfill following processing by pressure sterilisation and permanent marking of the resulting material;
  - dispatched to an ABP approved OF/SI manufacturing plant;
  - dispatched to an ABP approved compost or biogas plant which is permitted to take in such derived products;
  - used as a fuel for combustion;
  - dispatched to an ABP plant approved for the manufacture of derived products referred to Articles 33, 34 and 36 of Regulation (EC) No. 1069/2009. A DAFM authorised officer must be informed in advance of such end-usage and approve such usage prior to dispatching consignments.

- The operator must ensure that ABP or derived product dispatched from the plant is transported directly to an approved plant of destination. The approval must be in date and valid.

- ABP or derived products suspected or discovered not to comply with the legislation or the specific plant approval requirements may not leave the plant until these products have been brought to the attention of a DAFM authorized officer who should agree a plan for them with plant management.

5.2 DOCUMENTATION

- The operator must keep and up-to-date dispatch register, completed appropriately, in chronological order including:
  - a description of the ABP (including waste), intermediate products or derived products dispatched (including quantities);
  - dates of dispatch;
  - a batch reference or consignment number;
  - a health certificate or commercial document reference number;

- the name and address and country of the premises of dispatch (and approval number);
- the name and address of the carrier/haulier and the receptacle registration number (if applicable);
- date of notification of the Regional Veterinary Office of dispatch (if relevant e.g. for export or trade);
- weights of consignments of outgoing material (preferably using a plant's own weighbridge);
- seal numbers of consignments (if applicable);
- a reference to indicate proof of arrival at destination.

- A fully completed commercial document must accompany each load of ABP leaving the plant. The commercial document must be assigned a unique identifiable number. The commercial document must be produced in quadruplicate (1 original and 3 copies). The original must remain at the plant of origin, the transporter must retain one copy and the premises of destination the other. The fourth copy is signed by the premises of destination and returned to the plant of origin.

  In the case of ABP or derived product being dispatched to other EU countries , the operator must ensure that an Article 48 licence is in place that authorizes the dispatch of Cat2 ABP or derived product to another member state. The operator responsible for the plant of origin must apply to the competent authority of the member state of destination seeking an Article 48 licence to dispatch consignments to the operator of the plant of destination. An A3 EU commercial document must be used and a Traces message generated by the business operator informing DAFM and the competent authority of the member state of destination that a consignment is being dispatched. DAFM must inform the competent authority of the plant of destination by a traces message of the dispatch of each consignment dispatched to another member state.

  The competent authority of the plant of destination must inform DAFM of the arrival of the consignment at the plant of destination.

  Operators must keep the copies of commercial documents for all outgoing loads filed and in date order.

- Copies of all health certificates issued must be retained. Health certificates may only be drawn up and signed by DAFM officials.

- The operator must retain proof of destination for all ABP consignments or consignments of products manufactured or derived from ABP dispatched from the plant. This proof of destination would typically be the signed or stamped copy of the commercial document returned by the customer (consignee) or notification of arrival on the TRACES system.

CONTACT DETAILS

For further information contact:

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